

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

LOCHT et al

Atty. Ref.: 960-25

Serial No.: 08/765,287

Group Art Unit: 1641

Filed: September 12, 1997

Examiner: Ryan, V.

For: **RECOMBINANT PROTEINS OF FILAMENTOUS  
HAEMAGGLUTININ OF BORDETELLA,  
PARTICULARLY BORDETELLA PERTUSSIS,  
METHOD FOR PRODUCING SAME, AND USES  
THEREOF FOR PRODUCING FOREIGN PROTEINS  
OR VACCINATING ACTIVE PRINCIPLES**

\* \* \* \* \*

October 28, 1998

**RESPONSE TO RESTRICTION REQUIREMENT**

Hon. Commissioner of Patents  
and Trademarks  
Washington, DC 20231

Sir:

In response to the Examiner's requirement for restriction, set forth in the Office Action dated September 28, 1998, Applicants elect the subject matter of Group I (claims 1-22 and 26-29) with traverse.

Group I relates to DNA, methods, compositions and host cells.

Group II relates to proteins and compositions comprising the same.

Applicants submit that the subject matter of Group I and that of Group II is linked by a single general inventive concept and thus, should be prosecuted in the same application.

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Oct 28  
1998*

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As noted by the Examiner, the assessment of Unity of the present application should be made in accordance with the PCT rules.

Rule 13.2 PCT provides that, where a group of inventions is claimed in one application, the Unity of Invention is present if there is a technical relationship between those inventions involving one or more of the same or corresponding special technical features. It is believed that there is a clear technical relationship between the subject matter of Groups I and II. Indeed, the subject matter of Group I relates to nucleic acids encoding a hybrid polypeptide, host cells, compositions and methods thereof. Group II relates to polypeptides encoded by the nucleic acids of Group I. Because the polypeptides represent the expression products of the nucleic acids of Group I, there exists a clear structural and functional relationship between these two groups. A structural relationship exists because the primary structure of the polypeptide is directly governed by the structure of the nucleic acid, and a functional relationship exists because the activity of the polypeptide is determined by the nature of the DNA sequence of the nucleic acids of Group I.

While the references quoted by the Examiner (i.e., Menozzi et al, and Miller et al) might be relevant to the examination of this application, they do not alter this technical relationship between Groups I and II. In this regard, it should be noted that these references have been cited in the Search Report that issued

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in connection with the corresponding international application and considered by the examiner during International Preliminary Examination Report (Miller et al) without leading to any lack of Unity objection.

Furthermore, the Examiner indicates that although the DNA can be used to prepare polypeptides, "the polypeptides can also be produced synthetically". Applicants respectfully disagree. Indeed, the claimed polypeptides comprise at least a portion of the N-terminal region of Fha, which is a 220 Kda molecule and thus comprises around 1600 amino acids. As the Examiner will appreciate, although theoretically possible, it would be practically impossible to chemically synthesize such a polypeptide. Actually, to Applicants' knowledge, no synthetic polypeptide of such length has ever been produced in a reproducible manner.

Accordingly, Applicants submit that the subject matter of Group I and that of II are technically related by a single general inventive concept and should be prosecuted in one single application, in accordance with Rule 13.1 PCT.

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An early and favorable Action on the merits is awaited.

Respectfully submitted,

**NIKON & VANDERHVE, P.C.**

By Mary J. Wilson  
Mary J. Wilson  
Reg. No. 32,955

MJW:tat

1100 North Glebe Road  
8<sup>th</sup> Floor  
Arlington, Virginia 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100

FAX RECEIVED

OCT 29 1998

**OFFICIAL****Nixon & Vanderhye PC**  
ATTORNEY AT LAW

GROUP 1600

8TH FLOOR  
1100 NORTH GLEBE ROAD  
ARLINGTON, VIRGINIA 22201-4714TELEPHONE: (703) 816-4000  
FACSIMILE: (703) 816-41  
WRITER'S DIRECT DIAL NUMB  
**(703) 816-4011****FACSIMILE COVER SHEET****PLEASE DELIVER IMMEDIATELY!!!!**Our Ref.: 960-25Your Ref.: \_\_\_\_\_ Date: October 28, 1998To: Examiner Ryan, V. - Group: 1641Firm: USPTOFacsimile No.: (703) 305-7939From: Mary J. WilsonNumber of Pages (including cover sheet): 7(IF YOU DO NOT RECEIVE ALL OF THE PAGES OR ENCOUNTER DIFFICULTIES IN TRANSMISSION,  
PLEASE CONTACT US IMMEDIATELY AT (703-816-4000).Tabitha A. Trice  
FACSIMILE OPERATOR

ATTACHMENT/S: OFFICIAL RESPONSE TO RESTRICTION REQUIREMENT

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PRODUCING FOREIGN PROTEINS OR VACCINATING ACTIVE PRINCIPLES**MESSAGE:****CONFIDENTIALITY NOTE**

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